

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

ASTELLAS PHARMA INC., ASTELLAS	)	
IRELAND CO., LTD. and ASTELLAS	)	
PHARMA GLOBAL DEVELOPMENT,	)	
INC.,	)	C.A. No. _____
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
AUROBINDO PHARMA LTD.,	)	
AUROBINDO PHARMA USA, INC.,	)	
AUROLIFE PHARMA LLC, ACTAVIS	)	
ELIZABETH LLC, ACTAVIS LLC, TEVA	)	
PHARMACEUTICALS USA, INC.,	)	
ZYDUS PHARMACEUTICALS (USA),	)	
INC., CADILA HEALTHCARE LTD.	)	
(d/b/a ZYDUS CADILA), LUPIN LTD. and	)	
LUPIN PHARMACEUTICALS, INC.	)	
	)	
Defendants.	)	

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Astellas Pharma Inc., Astellas Ireland Co., Ltd. and Astellas Pharma Global Development, Inc. (collectively, “Astellas” or “Plaintiffs”), by their undersigned attorneys, hereby allege as follows:

**NATURE OF ACTION**

1. This is an action for patent infringement of United States Patent No. 10,842,780 (“the ’780 Patent”), arising under the United States patent laws, Title 35, United States Code. This action relates to the Abbreviated New Drug Applications (“ANDAs”) submitted by the above-named Defendants under Section 505(j) of the Federal Food, Drug and Cosmetic Act (“FDCA”), 21 U.S.C. § 355(j), seeking United States Food and Drug Administration (“FDA”) approval to market generic pharmaceutical products.

## **THE PARTIES**

### **A. Astellas Pharma Inc., Astellas Ireland Co., Ltd. and Astellas Pharma Global Development, Inc.**

2. Plaintiff Astellas Pharma Inc. (“API”) is a corporation organized and existing under the laws of Japan, having its principal place of business at 2-5-1, Nihonbashi-Honcho, Chuo-Ku, Tokyo 103-8411, Japan. API was formed on April 1, 2005, from the merger of Yamanouchi Pharmaceutical Co., Ltd. and Fujisawa Pharmaceutical Co., Ltd.

3. Plaintiff Astellas Ireland Co., Ltd. (“AICL”) is a corporation organized and existing under the laws of Ireland, having its principal place of business at Damastown Road, Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland. AICL is a subsidiary of Plaintiff API.

4. Plaintiff Astellas Pharma Global Development, Inc. (“APGD”) is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1 Astellas Way, Northbrook, Illinois 60062. APGD is a subsidiary of Plaintiff API.

### **B. Aurobindo Pharma Ltd., Aurobindo Pharma USA, Inc. and Aurolife Pharma LLC (collectively, “Aurobindo”)**

5. On information and belief, Defendant Aurobindo Pharma Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Plot No. 2, Maitrivihar, Ameerpet, Hyderabad-500038, Telangana, India. On information and belief, Aurobindo Pharma Ltd. is in the business of, *inter alia*, developing, manufacturing and/or distributing generic drug products for marketing, sale, and/or use throughout the United States including in this judicial district.

6. On information and belief, Defendant Aurobindo Pharma USA, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 6 Wheeling Road, Dayton, New Jersey 08810. On information and belief, Aurobindo Pharma USA, Inc. is in the business of, *inter alia*, developing, manufacturing and/or distributing

generic drug products for marketing, sale, and/or use throughout the United States including in this judicial district.

7. On information and belief, Defendant Aurolife Pharma LLC is a limited liability company organized and existing under the laws of Delaware, having a principal place of business at 2400 Route 130 North, Dayton, New Jersey 08810. On information and belief, Aurolife Pharma LLC is in the business of, *inter alia*, developing, manufacturing and/or distributing generic drug products for marketing, sale, and/or use throughout the United States including in this judicial district.

8. By a letter dated March 9, 2021, (“Aurobindo’s Notice Letter”) Aurobindo notified Plaintiffs that Aurobindo had submitted to FDA ANDA No. 209413 for 50 mg mirabegron extended-release tablets (“Aurobindo ANDA”), a drug product that is a generic version of Myrbetriq® extended-release tablets, in the 50 mg strength (“Aurobindo’s ANDA Product”). On information and belief, the purpose of Aurobindo’s submission of the Aurobindo ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Aurobindo’s ANDA Product prior to the expiration of the ’780 Patent.

9. In Aurobindo’s Notice Letter, Aurobindo notified Plaintiffs that, as a part of the Aurobindo ANDA, Aurobindo had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the ’780 Patent, asserting it is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Aurobindo’s ANDA Product.

10. On information and belief, and consistent with their past practices, Aurobindo Pharma Ltd., Aurobindo Pharma USA, Inc. and Aurolife Pharma LLC acted collaboratively in the preparation and submission of ANDA No. 209413.

11. On information and belief, and consistent with their past practices, following any FDA approval of ANDA No. 209413, Aurobindo Pharma Ltd., Aurobindo Pharma USA, Inc. and Aurolife Pharma LLC will work in concert with one another to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 209413 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

**C. Actavis Elizabeth LLC, Actavis LLC and Teva Pharmaceuticals USA, Inc. (collectively, “Actavis”)**

12. On information and belief, Defendant Actavis Elizabeth LLC is a limited liability company organized and existing under the laws of Delaware, having a principal place of business at 200 Elmora Avenue, Elizabeth, New Jersey, 07202. On information and belief, Actavis Elizabeth LLC is in the business of, *inter alia*, developing, manufacturing and/or distributing generic drug products for marketing, sale, and/or use throughout the United States including in this judicial district.

13. On information and belief, Defendant Actavis LLC is a limited liability company organized and existing under the laws of Delaware, having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. On information and belief, Actavis LLC is in the business of, *inter alia*, developing, manufacturing and/or distributing generic drug products for marketing, sale, and/or use throughout the United States including in this judicial district.

14. On information and belief, Defendant Teva Pharmaceuticals USA Inc. (“Teva”) is a corporation organized and existing under the laws of Delaware, having a principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054. On information and belief, Teva is in the business of, *inter alia*, developing, manufacturing and/or distributing generic drug

products for marketing, sale, and/or use throughout the United States including in this judicial district.

15. On information and belief, on or about August 2, 2016, Teva acquired Actavis's Generics business, including Actavis Elizabeth LLC and Actavis LLC.

16. On information and belief, Actavis Elizabeth LLC is a wholly owned subsidiary of Actavis LLC, which is a wholly owned subsidiary of Teva.

17. By a letter dated March 16, 2021 ("Actavis's Notice Letter"), Actavis notified Plaintiffs that Actavis had submitted to FDA ANDA No. 209368 for Mirabegron Extended-Release Tablets, 25 mg and 50 mg ("Actavis ANDA"), a drug product that is a generic version of Myrbetriq® extended-release tablets, in the 25 mg and 50 mg strengths ("Actavis's ANDA Product"). On information and belief, the purpose of Actavis's submission of the Actavis ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Actavis's ANDA Product prior to the expiration of the '780 Patent.

18. In Actavis's Notice Letter, Actavis notified Plaintiffs that, as a part of the Actavis ANDA, Actavis had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '780 Patent, asserting that it is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Actavis's ANDA Product.

19. On information and belief, and consistent with their past practices, Actavis Elizabeth LLC and Actavis LLC acted collaboratively in the preparation and submission of ANDA No. 209368.

20. On information and belief, and consistent with their past practices, following any FDA approval of ANDA No. 209368, Actavis Elizabeth LLC, Actavis LLC and Teva will work

in concert with one another to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 209368 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

**D. Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. (d/b/a Zydus Cadila) (collectively, “Zydus”)**

21. On information and belief, Defendant Zydus Pharmaceuticals (USA) Inc. is a corporation organized and existing under the laws of New Jersey, having a principal place of business at 73 Route 31 North, Pennington, New Jersey 08534. On information and belief, Zydus Pharmaceuticals (USA) Inc. is in the business of, *inter alia*, developing, manufacturing and/or distributing generic drug products for marketing, sale, and/or use throughout the United States including in this judicial district.

22. On information and belief, Defendant Cadila Healthcare Ltd. (d/b/a Zydus Cadila) (“Zydus Cadila”) is a corporation organized and existing under the laws of India, having a principal place of business at Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S. G. Highway, Ahmedabad 382 481, India. On information and belief, Zydus Cadila is in the business of, *inter alia*, developing, manufacturing and/or distributing generic drug products for marketing, sale, and/or use throughout the United States including in this judicial district.

23. By a letter dated March 3, 2021 (“Zydus’s Notice Letter”), Zydus notified Plaintiffs that Zydus had submitted to FDA ANDA No. 209488 for mirabegron extended-release oral tablets, 25 mg and 50 mg (“Zydus ANDA”), a drug product that is a generic version of Myrbetriq® extended-release tablets, in the 25 mg and 50 mg strengths (“Zydus’s ANDA Product”). On information and belief, the purpose of Zydus’s submission of the Zydus ANDA was to obtain

approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Zydus's ANDA Product prior to the expiration of the '780 Patent.

24. In Zydus's Notice Letter, Zydus notified Plaintiffs that, as a part of the Zydus ANDA, Zydus had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '780 Patent, asserting that it is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Zydus's ANDA Product.

25. On information and belief, and consistent with their past practices, Zydus Pharmaceuticals (USA) Inc. and Zydus Cadila acted collaboratively in the preparation and submission of ANDA No. 209488.

26. On information and belief, and consistent with their past practices, following any FDA approval of ANDA No. 209488, Zydus Pharmaceuticals (USA) Inc. and Zydus Cadila will work in concert with one another to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 209488 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

**E. Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively, "Lupin")**

27. On information and belief, Defendant Lupin Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at 3<sup>rd</sup> Floor, Kalpataru Inspire, Off. Western Expressway Highway, Santacruz (East), Mumbai 400 055, India. On information and belief, Lupin Ltd. is in the business of, *inter alia*, developing, manufacturing and/or distributing generic drug products for marketing, sale, and/or use throughout the United States including in this judicial district.

28. On information and belief, Defendant Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at

Harborplace Tower, 111 South Calvert Street, 21<sup>st</sup> Floor, Baltimore, MD 21292. On information and belief, Lupin Pharmaceuticals Inc. is in the business of, *inter alia*, developing, manufacturing and/or distributing generic drug products for marketing, sale, and/or use throughout the United States including in this judicial district.

29. By a letter dated February 8, 2021 (“Lupin’s Notice Letter”) Lupin notified Plaintiffs that Lupin had submitted to FDA ANDA No. 209485 for mirabegron “in the form of extended release tablets, each containing either 25 mg or 50 mg mirabegron as the active ingredient.” (“Lupin ANDA”), a drug product that is a generic version of Myrbetriq® extended-release tablets, in the 25 mg and 50 mg strengths (“Lupin’s ANDA Product”). On information and belief, the purpose of Lupin’s submission of the Lupin ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Lupin’s ANDA Product prior to the expiration of the ’780 Patent.

30. In Lupin’s Notice Letter, Lupin notified Plaintiffs that, as a part of the Lupin ANDA, Lupin had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the ’780 Patent, asserting that it is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Lupin’s ANDA Product.

31. On information and belief, and consistent with their past practices, Lupin Ltd. and Lupin Pharmaceuticals Inc. acted collaboratively in the preparation and submission of ANDA No. 209485.

32. On information and belief, and consistent with their past practices, following any FDA approval of ANDA No. 209485, Lupin Ltd. and Lupin Pharmaceuticals Inc. will work in concert with one another to make, use, offer to sell, and/or sell the generic drug products that are



the subject of ANDA No. 209485 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

### **JURISDICTION AND VENUE**

33. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

34. This Court has personal jurisdiction over each Defendant because, among other things, each has committed, or aided, abetted, contributed to, or participated in the commission of, tortious acts of patent infringement in filing each ANDA that has led to foreseeable harm and injury to Plaintiffs, and will imminently commit, or aid, abet, contribute to, or participate in the commission of, a tortious act of patent infringement by selling its ANDA Product which will lead to foreseeable harm and injury to Plaintiffs.

35. This Court also has personal jurisdiction over each Defendant because each of its affiliations with the State of Delaware, including in many instances by virtue of its incorporation in Delaware or the incorporation in Delaware of subsidiaries, are so continuous and systematic as to render each Defendant essentially at home in this forum.

36. This Court also has personal jurisdiction over Aurobindo Pharma Ltd., Cadila Healthcare Ltd. and Lupin Ltd. pursuant to Fed. R. Civ. P. 4(k)(2) because (a) Astellas's claims arise under federal law; (b) as foreign defendants, Aurobindo Pharma Ltd., Cadila Healthcare Ltd. and Lupin Ltd. are not subject to jurisdiction in any state's courts of general jurisdiction; and (c) Aurobindo Pharma Ltd., Cadila Healthcare Ltd. and Lupin Ltd. have sufficient contacts within the United States as a whole, including but not limited to preparing and submitting an ANDA to FDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Aurobindo Pharma Ltd., Cadila Healthcare Ltd. and Lupin Ltd. satisfies due process.

37. This Court also has personal jurisdiction over each Defendant because each has frequently availed itself of the legal protections of the State of Delaware by, among other things, selecting the State of Delaware as the place of incorporation for itself and their subsidiaries and admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware, including in related Myrbetriq® litigations. See e.g. *Astellas Pharma Inc. et al. v. Sandoz Inc. et al.*, C.A. No. 20-1589-JFB-CJB (D. Del.), D.I. 47, 52, 78; *Acadia Pharmaceuticals Inc. v. Zydus Pharmaceuticals (USA) Inc. et al.*, C. A. No. 20-1021 (D. Del.), D.I. 9; *Astellas Pharma Inc. et al. v. Aurobindo Pharma Ltd. et al.*, C.A. No. 16-942 (D. Del.), D.I. 22; *Astellas Pharma Inc. et al. v. Lupin Ltd. et al.*, C.A. No. 16-908 (D. Del.), D.I. 20; *Astellas Pharma Inc. et al. v. Actavis Elizabeth LLC. et al.*, C.A. No. 16-905 (D. Del.), D.I. 21.

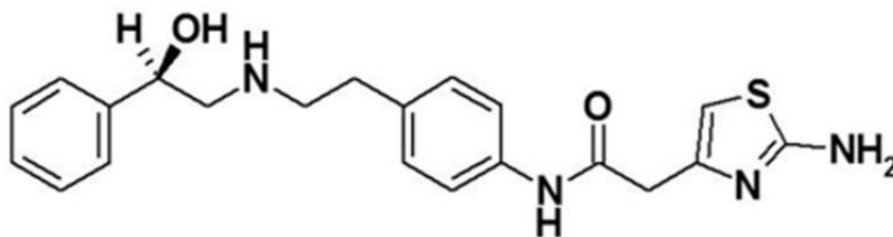
38. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over each Defendant.

39. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 1400(b) and/or Fed. R. Civ. P. 4(k)(2).

### **MYRBETRIQ® TABLETS**

40. APGD holds approved New Drug Application (“NDA”) No. 202611 for Myrbetriq® extended-release tablets, 25 mg and 50 mg, which contain the active ingredient, mirabegron. FDA approved NDA No. 202611 on June 28, 2012 for both the 25 mg and 50 mg extended-release Myrbetriq® tablets.

41. Mirabegron has been referred to chemically as, *inter alia*, (R)-2-(2-aminothiazol-4-yl)-4'-[2-(2-hydroxy-2-phenylethyl)amino]ethyl]acetic acid anilide, (R)-2-(2-aminothiazol-4-yl)-4'-[2-[(2-hydroxy-2-phenylethyl)amino]ethyl]acetanilide, and 2-(2-aminothiazol-4-yl)-N-[4-(2-[(2R)-2-hydroxy-2-phenylethyl]amino)ethyl]phenyl]acetamide. Mirabegron can be depicted as, *inter alia*, the following formula:



42. Myrbetriq® extended-release tablets, containing 25 mg or 50 mg of mirabegron (“Myrbetriq® Tablets”), are indicated for the treatment of overactive bladder (“OAB”) with symptoms of urge urinary incontinence, urgency, and urinary frequency.

43. Myrbetriq® Tablets comprise a sustained release hydrogel-forming formulation containing, *inter alia*, polyethylene oxide and polyethylene glycol as inactive ingredients within the tablet formulation, which function as a means for forming a hydrogel and a means for ensuring penetration of water into the tablets.

44. For quality control purposes in the U.S. market, Myrbetriq® Tablets are subjected to dissolution testing using the United States Pharmacopeia (“USP”) Apparatus I. A dissolution test evaluates the rate and extent that a compound forms a solution under carefully controlled conditions. Within the context of regulatory approval, the USP dissolution test helps safeguard against the release of drug products that do not perform acceptably. USP Apparatus I (basket) and II (paddle) provide a platform to evaluate the *in vitro* performance of dosage forms using standardized conditions. These two apparatus, and associated procedures, have become widely used and accepted.

45. When measured in accordance with the United States Pharmacopeia (“USP”) dissolution apparatus II, using 900 mL of USP buffer and having a pH of 6.8 at a paddle rotation speed of 200 rpm (“USP II Method”), the Myrbetriq® Tablets release 39% or less of mirabegron after 1.5 hours, and at least 75% mirabegron after 7 hours.

**THE PATENT-IN-SUIT**

46. The United States Patent & Trademark Office (“PTO”) duly and legally issued the ’780 Patent, entitled “Pharmaceutical Composition for Modified Release,” on November 24, 2020. A true and correct copy of the ’780 Patent is attached as **Exhibit A**.

47. The ’780 Patent is listed in FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”) in connection with Myrbetriq® Tablets.

48. API is the record owner and assignee of the ’780 Patent.

49. The ’780 Patent will expire no earlier than September 28, 2029.

50. AICL is the exclusive licensee of the ’780 Patent with the rights to develop, import, market, sell, distribute, and promote any and all pharmaceutical formulations in finished package forms which contain mirabegron as the active ingredient in the United States.

51. APGD has contracted with AICL to, *inter alia*, clinically develop mirabegron, prepare and submit NDA No. 202611 for marketing approval of Myrbetriq® Tablets in the United States.

52. AICL has contracted with Astellas Pharma US, Inc., a subsidiary of API to, *inter alia*, market and sell Myrbetriq® Tablets, in the United States on its behalf.

53. Myrbetriq® Tablets are covered by one or more claims of the ’780 Patent.

**MIRABEGRON ANDA FILERS**

54. In June 2013, FDA issued a notice in the Federal Register (78 Fed. Reg. 37230 at 31 (June 20, 2013)) regarding bioequivalence guidance to be published on its website for mirabegron ANDAs. On its website, FDA lists the following dissolution requirements for mirabegron ANDA filers in order to establish bioequivalence with Myrbetriq® Tablets (“Mirabegron Bioequivalence Guidance”):

Drug Name	Dosage Form	USP Apparatus	Speed (RPMs)	Medium	Volume (mL)	Recommended Sampling Times (minutes)	Date Updated
Mirabegron	Tablet (Extended Release)	I (Basket)	100	Phosphate Buffer, pH 6.8	900	1, 3, 5, 7, 8.5, 10 and 12 hours	05/09/2013

55. On information and belief, each mirabegron ANDA filer will be required to meet this dissolution method, or an equivalent dissolution method, to meet its bioequivalence requirements for its proposed ANDA product using Myrbetriq® Tablets as the reference standard. On information and belief, a proposed mirabegron ANDA product will have equivalent dissolution properties to Myrbetriq® Tablets as measured by USP Apparatus I and II.

### **CLAIMS FOR RELIEF**

#### **COUNT I: INFRINGEMENT OF THE '780 PATENT BY AUROBINDO**

56. Plaintiffs incorporate by reference and reallege paragraphs 1 through 55 above as though fully restated herein.

57. Aurobindo, by filing ANDA No. 209413, has necessarily represented to FDA that, upon approval, Aurobindo's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as Myrbetriq® Tablets, and will be bioequivalent to Myrbetriq® Tablets.

58. Aurobindo has indicated, including *inter alia* via Aurobindo's Notice Letter, its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Aurobindo's ANDA Product prior to the expiration of the '780 Patent.

59. On information and belief, and as required by the Mirabegron Bioequivalence Guidance, Aurobindo uses the dissolution method (or its equivalent) to establish Aurobindo's ANDA Product is bioequivalent to Myrbetriq® Tablets. On information and belief, Aurobindo's ANDA Product will have equivalent dissolution properties, as measured by USP Apparatus I and

II, to Myrbetriq® Tablets, which uses a hydrogel formulation. On information and belief, because of the dissolution requirements contained within the Mirabegron Bioequivalence Guidance, including the use of Myrbetriq® Tablets as the reference standard, Aurobindo's ANDA Product uses a hydrogel formulation, the same as or equivalent to the Myrbetriq® Tablets formulation, that is covered by one or more claims of the '780 Patent.

60. On information and belief, Aurobindo relied on, *inter alia*, Aurobindo's dissolution data to conclude that Aurobindo's ANDA Product is bioequivalent to Astellas's Myrbetriq® Tablets.

61. In Aurobindo's Notice Letter, Aurobindo does not deny that Aurobindo's ANDA Product is covered by one or more claims of the '780 Patent.

62. Aurobindo's submission of ANDA No. 209413 seeking approval to engage in the commercial manufacture, use, offer to sell, or sale of Aurobindo's ANDA Product, prior to the expiration of the '780 Patent, constitutes infringement of one or more of the claims of the '780 Patent under 35 U.S.C. § 271(e)(2)(A).

63. Unless Aurobindo is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Aurobindo's infringement of the '780 Patent. Plaintiffs do not have an adequate remedy at law.

64. Plaintiffs are commencing this action within 45 days of receiving Aurobindo's Notice Letter pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

## **COUNT II: INFRINGEMENT OF THE '780 PATENT BY ACTAVIS**

65. Plaintiffs incorporate by reference and reallege paragraphs 1 through 64 above as though fully restated herein.

66. Actavis, by filing ANDA No. 209368, has necessarily represented to FDA that, upon approval, Actavis's ANDA Product will have the same active ingredient, method of

administration, dosage form, and dosage amount as Myrbetriq® Tablets, and will be bioequivalent to Myrbetriq® Tablets.

67. Actavis has indicated, including *inter alia* via Actavis's Notice Letter, its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Actavis's ANDA Product prior to the expiration of the '780 Patent.

68. On information and belief, and as required by the Mirabegron Bioequivalence Guidance, Actavis uses the dissolution method (or its equivalent) to establish Actavis's ANDA Product is bioequivalent to Myrbetriq® Tablets. On information and belief, Actavis's ANDA Product will have equivalent dissolution properties, as measured by USP Apparatus I and II, to Myrbetriq® Tablets, which uses a hydrogel formulation. On information and belief, because of the dissolution requirements contained within the Mirabegron Bioequivalence Guidance, including the use of Myrbetriq® Tablets as the reference standard, Actavis's ANDA Product uses a hydrogel formulation, the same as or equivalent to the Myrbetriq® Tablets formulation, that is covered by one or more claims of the '780 Patent.

69. In Actavis's Notice Letter, Actavis does not deny that Actavis's ANDA Product is covered by one or more claims of the '780 Patent.

70. Actavis's submission of ANDA No. 209368 seeking approval to engage in the commercial manufacture, use, offer to sell, or sale of Actavis's ANDA Product, prior to the expiration of the '780 Patent, constitutes infringement of one or more of the claims of the '780 Patent under 35 U.S.C. § 271(e)(2)(A).

71. Unless Actavis is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Actavis's infringement of the '780 Patent. Plaintiffs do not have an adequate remedy at law.

72. Plaintiffs are commencing this action within 45 days of receiving Actavis's Notice Letter pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

**COUNT III: INFRINGEMENT OF THE '780 PATENT BY ZYDUS**

73. Plaintiffs incorporate by reference and reallege paragraphs 1 through 72 above as though fully restated herein.

74. Zydus, by filing ANDA No. 209488 has necessarily represented to FDA that, upon approval, Zydus's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as Myrbetriq® Tablets, and will be bioequivalent to Myrbetriq® Tablets.

75. Zydus has indicated, including *inter alia* via Zydus's Notice Letter, its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Zydus's ANDA Product prior to the expiration of the '780 Patent.

76. On information and belief, and as required by the Mirabegron Bioequivalence Guidance, Zydus uses the dissolution method (or its equivalent) to establish Zydus's ANDA Product is bioequivalent to Myrbetriq® Tablets. On information and belief, Zydus's ANDA Product will have equivalent dissolution properties, as measured by USP Apparatus I and II, to Myrbetriq® Tablets, which uses a hydrogel formulation. On information and belief, because of the dissolution requirements contained within the Mirabegron Bioequivalence Guidance, including the use of Myrbetriq® Tablets as the reference standard, Zydus's ANDA Product uses a hydrogel formulation, the same as or equivalent to the Myrbetriq® Tablets formulation, that is covered by one or more claims of the '780 Patent.

77. On information and belief, Zydus relied on, *inter alia*, Zydus's dissolution data to conclude that Zydus's ANDA Product is bioequivalent to Astellas's MYRBETRIQ® Tablets.



78. In Zydus's Notice Letter, Zydus does not deny that Zydus's ANDA Product is covered by one or more claims of the '780 Patent.

79. Zydus's submission of ANDA No. 209488 seeking approval to engage in the commercial manufacture, use, offer to sell, or sale of Zydus's ANDA Product, prior to the expiration of the '780 Patent, constitutes infringement of one or more of the claims of the '780 Patent under 35 U.S.C. § 271(e)(2)(A).

80. Unless Zydus is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Zydus's infringement of the '780 Patent. Plaintiffs do not have an adequate remedy at law.

81. Plaintiffs are commencing this action within 45 days of receiving Zydus's Notice Letter pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

**COUNT IV: INFRINGEMENT OF THE '780 PATENT BY LUPIN**

82. Plaintiffs incorporate by reference and reallege paragraphs 1 through 81 above as though fully restated herein.

83. Lupin, by filing ANDA No. 209485, has necessarily represented to FDA that, upon approval, Lupin's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as Myrbetriq® Tablets, and will be bioequivalent to Myrbetriq® Tablets.

84. Lupin has indicated, including *inter alia* via Lupin's Notice Letter, its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Lupin's ANDA Product prior to the expiration of the '780 Patent.

85. On information and belief, and as required by the Mirabegron Bioequivalence Guidance, Lupin uses the dissolution method (or its equivalent) to establish Lupin's ANDA Product is bioequivalent to Myrbetriq® Tablets. On information and belief, Lupin's ANDA

Product will have equivalent dissolution properties, as measured by USP Apparatus I and II, to Myrbetriq® Tablets, which uses a hydrogel formulation. On information and belief, because of the dissolution requirements contained within the Mirabegron Bioequivalence Guidance, including the use of Myrbetriq® Tablets as the reference standard, Lupin's ANDA Product uses a hydrogel formulation, the same as or equivalent to the Myrbetriq® Tablets formulation, that is covered by one or more claims of the '780 Patent.

86. On information and belief, Lupin relied on, *inter alia*, Lupin's dissolution data to conclude that Lupin's ANDA Product is bioequivalent to Astellas's Myrbetriq® Tablets.

87. Lupin's submission of ANDA No. 209485 seeking approval to engage in the commercial manufacture, use, offer to sell, or sale of Lupin's ANDA Product, prior to the expiration of the '780 Patent, constitutes infringement of one or more of the claims of the '780 Patent under 35 U.S.C. § 271(e)(2)(A).

88. Unless Lupin is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Lupin's infringement of the '780 Patent. Plaintiffs do not have an adequate remedy at law.

89. Plaintiffs are commencing this action within 45 days of receiving Lupin's Notice Letter pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

#### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs API, AICL, and APGD, pray for a judgment in their favor and against Defendants, and respectfully request the following relief:

A. A judgment that each Defendant's submission and maintenance of its ANDA (i.e., the Aurobindo ANDA, Actavis ANDA, Zydus ANDA, or Lupin ANDA) constituted an act of infringement of the '780 Patent;

B. A judgment (or a declaration) that each Defendant's making, using, offering to sell, or selling in the United States or importing into the United States of its respective Proposed ANDA Product (i.e., Aurobindo's ANDA Product, Actavis's ANDA Product, Zydus's ANDA Product, or Lupin's ANDA Product) will infringe the '780 Patent;

C. A permanent injunction restraining and enjoining each Defendant, its affiliates, subsidiaries, and each of their officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of its respective Proposed ANDA Product until the expiration of the '780 Patent, including any extensions and/or periods of exclusivity to which Plaintiffs and/or the '780 Patent are or become entitled;

D. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of each Defendant's ANDA shall be a date that is not earlier than the expiration date of the '780 Patent, including any extensions and/or periods of exclusivity to which Plaintiffs and/or the '780 Patent are or become entitled;

E. Damages, including monetary and other relief, to Plaintiffs if any Defendant engages in commercial manufacture, use, offers to sell, sale, or importation into the United States of its Proposed ANDA Product, prior to the expiration date of the '780 Patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

F. A declaration that this case is "exceptional" within the meaning of 35 U.S.C. § 285 and an award of reasonable attorney fees, costs, expenses, and disbursements of this action; and

G. Such other and further relief as the Court may deem just and proper.

Dated: March 24, 2021

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